

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A drug delivery device [(10)] comprising:
  - i) a housing [(12)];
  - ii) a means [(14)] for generating a force capable of pushing a drug [(16)] from a packaging [(18)] into a human or animal body;
  - iii) a means [(20)] for transmitting said force to push the drug [(16)] from the packaging [(18)] into the human or animal body; and
  - iv) a means [(38, 42b)] for triggering the device.
  
2. (Currently Amended) A drug delivery device as claimed in claim 1 wherein the housing defines:
  - i) an upper barrel [(28)], at one end of the device which houses the force generating means [(14)]; and
  - ii) a lower barrel [(30)], at the end remote from the upper barrel, which houses:
    - a) a packaged drug [(100)]; and
    - b) the means [(20)] for transmitting said force to push the drug [(16)] from the packaging [(18)]

said lower barrel being in operative communication with said upper barrel and said packaged drug [(100)].
  
3. (Currently Amended) A drug delivery device [(10)] as claimed in claim 2 further comprising:
  - v) a means [(22)] for receiving the packaged drug [(100)]; and
  - vi) a means [(24)] for priming the device.
  
4. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ Claim 1 wherein the means [(14)] for generating a force capable of pushing a drug [(16)] from a packaging [(18)] into a human or animal body delivers a force of from 10 – 40N.

5. (Currently Amended) A drug delivery device as claimed in [any] claim 2 wherein the means [(20)] for transmitting said force to push the drug [(16)] from the packaging [(18)] causes the drug to be pushed from the packaging at less than 10m/s.

6. (Currently Amended) A drug delivery device as claimed in claim 3 wherein said packaged drug [(100)] is slidably disposed in the means [(22)] for receiving the packaged drug.

7. (Currently Amended) A drug delivery device as claimed in ~~any of claims 2 to 6~~ claim 2 wherein the packaged drug [(100)] is slidably disposed in the lower barrel [(30)] and comprises a packaging [(18)] containing a drug [(16)], said packaging comprising a housing [(18a, 18b)] having a channel ~~(106; 106a, 106b)~~ running there through in which is disposed a drive pin or other element [(108)], a skin piercing means [(110; 112)] and the drug [(16)]; said housing further comprising

- i) a region [(102)] allowing the packaged drug to be slidably mounted to the drug delivery device [(10)] at receiving means [(22)]; and
- ii) an end [(104)] adapted to engage and tension the skin.

8. (Currently Amended) A drug delivery device as claimed in claim 7 wherein the skin piercing means is a pioneer projectile [(110)], a syringe needle [(112)] or the head of a drug splinter.

9. (Currently Amended) A drug delivery device as claimed in claim 7 [or 8] wherein the drive pin or other element [(108)] has a flat or enlarged head [(108a)].

10. (Currently Amended) A drug delivery device as claimed in claim 7[, 8 or 9] further comprising a resilient means [(114)] below or otherwise in association with the drive pin or other elements [(108)] to ensure the drive pin is withdrawn after use.

11. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ claim 1 wherein the means [(14)] for generating the force capable of pushing the drug [(16)] is a spring.

12. (Original) A drug delivery device as claimed in claim 11 wherein the spring is a coil or gas spring.

13. (Currently Amended) A drug deliver device as claimed in claim[[s]] 11 [or 12] wherein the force generated by the spring is adjustable.

14. (Currently Amended) A drug delivery device as claimed in claim 13 wherein a screw cap [[(32)]] and compression bar [[(34)]] provide a means for adjusting the force generated by the spring.

15. (Currently Amended) A drug deliver device as claimed in [any of] claim[s] 11 [-14] further comprising a spring follower [[(36)]].

16. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ Claim 7 wherein the means [[(20)]] for transmitting the force is a striker.

17. (Original) A drug delivery device as claimed in claim 16 wherein the striker is a hammer.

18. (Currently Amended) A drug delivery device as claimed in claim 16 [or 17] wherein a region [[(38)]] of the striker is shaped to fit a correspondingly shaped surface [[(42b)]] in a wall [[(42)]] separating the upper [[(28)]] and lower [[(30)]] barrels defined by the housing [[(12)]] such that the striker [[(20)]] is aligned to strike the drive pin [[(108)]] or other element in the packaged drug [[(100)]] on actuation.

19. (Currently Amended) A drug delivery device as claimed in claim 18 wherein the striker comprises a substantially frustoconical shoulder region [[(38)]] which engages a substantially frustoconical surface [[(42b)]] in the wall [[(42)]] separating the upper [[(28)]] and lower [[(30)]] barrels defined by the housing [[(12)]].

20. (Currently Amended) A drug delivery device as claimed in claim 15 wherein the means [[(20)]] for transmitting the force comprises a substantially conical end [[(20a)]] and the spring follower [[(36)]] has a correspondingly shaped recess [[(36a)]] in the underside thereof.

21. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ claim 16 wherein the packaged drug  $[(100)]$  and striker  $[(20)]$  are slidably mounted in the device such that the device can be [can be] primed by pushing the device against the skin.

22. (Currently Amended) A drug delivery device as claimed in ~~any of claims 19—21~~ claim 19 wherein the device comprises a slewing spring  $[(44)]$ , a sliding piston  $[(48)]$  having an aperture  $[(46)]$  therein and the striker  $[(20)]$ , all housed in the lower barrel  $[(30)]$  and the device is triggered by the sliding of the piston  $[(48)]$  up the lower barrel  $[(30)]$  until shoulder region  $[(38)]$  of the striker  $[(20)]$  engages shaped surface  $[(42b)]$  and aligns the striker with the aperture  $[(46)]$  in the sliding piston  $[(48)]$  such that the striker moves down the aperture under the action of the force generating means  $[(14)]$ .

23. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ claim 22 wherein the device is primed and actuated by a single action.

24. (Currently Amended) A device as claimed in claim 23 wherein pushing the packaged drug  $[(100)]$  up the lower barrel  $[(30)]$  with sufficient force causes the device to be primed and actuated.

25. (Currently Amended) A device as claimed in claim 23 [or 24] wherein the action of pushing the packaged drug up the lower barrel  $[(30)]$  with sufficient force causes the sliding piston  $[(48)]$  to move up the lower barrel  $[(30)]$  thereby causing the striker  $[(20)]$  to be pushed up the lower barrel  $[(30)]$  out of a first position in which it is not axially aligned with the aperture  $[(46)]$  in the sliding piston which operatively communicates with the packaged drug and at the same time acts on a spring follower  $[(36)]$  in the upper barrel  $[(28)]$  causing the spring  $[(14)]$  to be compressed and the device primed such that when the required delivery force is generated the striker  $[(20)]$  is axially aligned with the aperture  $[(46)]$  of the sliding piston  $[(48)]$  and is thus actuated such that the spring  $[(14)]$  acts through the spring follower  $[(36)]$  and striker  $[(20)]$  upon the drive pin  $[(108)]$  or a like element in the packaged drug  $[(100)]$  to deliver the drug  $[(16)]$  into the human or animal body.

26. (Currently Amended) A device as claimed in ~~claims 1—22~~ claim 1 wherein the device is primed and actuated by two separate actions.

27. (Currently Amended) A drug delivery device as claimed in ~~any of claims 2—25~~ claim 2 wherein the upper barrel and lower barrel are formed as separate components.

28. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ claim 1 wherein the drug is in a contained form.

29. (Original) A drug delivery device as claimed in claim 28 wherein the drug is either:

a liquid contained by a membrane;

a liquid with a viscosity of at least 500 centipoises, more preferably at least 5000 centipoises, and more preferably still at least 100,000 centipoises;

a semi solid,

a paste,

a gel or solid.

30. (Original) A drug delivery device as claimed in claim 1 further comprising a packaged drug as an integral part of the device.

31. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ claim 1 in which the device and/or packaged drug is sealed in a foil pouch ~~or the like~~ to prevent ingress of, ~~for example,~~ moisture, oxygen, light, bacteria or other drug degrading or contaminating agents.

32. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ wherein the tip of the pioneer projectile or needle is positioned a few mm in from end ~~[[104]]~~ of the packaging ~~[[18]]~~ such that it is moving when contacting the skin.

33. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ claim 7 wherein the end ~~[[104]]~~ about the exit of the channel ~~[[106]]~~ is in the form of a substantially annular ring located immediately about the channel ~~[[106]]~~ exit and having a depth and width in the range 1.5mm to 6 mm.

34. (Currently Amended) A drug delivery device as claimed in ~~any of the preceding claims~~ claim 1 further comprising a positive lock retention system to ensure the packaged drug ~~[[100]]~~ does not come away from the device under gravity yet is free to slide up the device.

35. (Currently Amended) A single use drug delivery device ~~[[10]]~~ comprising:

- i) a housing ~~{{(12)}}~~;
- ii) a pre-primed means ~~[[14]]~~ for generating a force capable of pushing a drug ~~[[16]]~~ from a packaging ~~[[18]]~~ into a human or animal body;
- iii) a means ~~[[20]]~~ for transmitting said force to push the drug ~~[[16]]~~ from the packaging ~~[[18]]~~ into the human or animal body;
- iv) a packaged drug ~~[[100]]~~ forming an integral part of the device; and
- v) a means for triggering the device.

36. (Original) A device as claimed in claim 35 wherein the means for triggering the device is an actuation button or like elements.

37. (Currently Amended) A single use drug delivery device ~~[[10]]~~ comprising:

- i) a housing ~~[[12]]~~;
- ii) a means ~~[[14]]~~ for generating a force capable of pushing a drug ~~[[16]]~~ from a packaging ~~[[18]]~~ into a human or animal body;
- iii) a means ~~[[20]]~~ for transmitting said force to push the drug ~~[[16]]~~ from the packaging ~~[[18]]~~ into the human or animal body;
- iv) a packaged drug ~~[[100]]~~ forming an integral part of the device;
- v) a means for priming ~~[[24]]~~ the device; and
- vi) a means ~~[[38, 42b]]~~ for triggering the device.

38. (Currently Amended) A packaging drug ~~[[100]]~~, for use with a drug delivery device, comprising a packaging ~~[[18]]~~ containing a drug ~~[[16]]~~, said packaging ~~[[18]]~~ comprising a housing ~~[[18a, 18b]]~~ having a channel ~~[[106]]~~ running there through in which is disposed a drive pin or other element ~~[[108]]~~, a skin piercing means ~~[[110; 112]]~~, and the drug ~~[[16]]~~,  
said housing ~~[[18a, 18b]]~~ further comprising

- i) a region  $[(102)]$  allowing the packaged drug  $[(100)]$  to be slidably mounted to the drug delivery device  $[(10)]$ ; and
- ii) an end  $[(104)]$  adapted to engage and tension the skin.

39. (Currently Amended) A packaged drug as claimed in claim 38 wherein the skin piercing means is a pioneer projectile  $[(110)]$ , syringe needle  $[(112)]$  or the head of a drug splinter.

40. (Currently Amended) A packaged drug as claimed in claim 38 [or 39] wherein the drug is in the form of a drug splinter.

41. (Currently Amended) A packaged drug as claimed in [any of] claim $[[s]]$  38 [to 40] wherein the housing is adapted to ensure the packaged drug positively locks to the device yet is free to slide therein.

42. (Currently Amended) A packaged drug  $[(100)]$  as claimed in [any of] claim $[[s]]$  38 [- 41] wherein the packaging  $[(18)]$  is substantially T-shaped.

43. (Currently Amended) A packaged drug as claimed in [any of] claim $[[s]]$  38 [- 42] wherein the drive pin has a flat and/or an enlarged head  $[(108a)]$ .

44. (Currently Amended) A packaged drug as claimed in [any of] claim $[[s]]$  38 [- 43] further comprising a resilient means  $[(114)]$  below the drive pin head to ensure the drive pin is withdrawn after use.

45. (Currently Amended) A packaged drug as claimed in [any of] claim $[[s]]$  38 [- 42] in which the packaging comprises at two-part housing  $[(18a, 18b)]$ .

46. (Currently Amended) A packaged drug as claimed in [any of] claim $[[s]]$  38 [to 42] comprising a pioneer projectile.

47. (Currently Amended) A packaged drug as claimed in [any of] claim $[[s]]$  38 [to 46] wherein the drug is held in a contained state.

48. (Currently Amended) A packaged drug as claimed in [any of] claim[s] ~~38 to 47~~ 39 wherein a hollow injection needle [(112)] is disposed in the channel [(106)] towards an [(104)] and a contained liquid drug [(16)] is disposed in the channel [(106)] there above.

49. (Currently Amended) A packaged drug as claimed in claim 48 wherein the contained liquid drug comprises a receptacle [(120)] slidably disposed in the channel and having a puncturable base [(122)], a top [(124)] sealable with the drive pin or element [(108)] for pushing

- i) the receptacle against the needle, and
- ii) the needle into the human or animal body

thereby causing the release of the drug [(16)] out of the channel and into the human or animal body when it is acted upon by the device [(10)]

50. (Currently Amended) A packaged drug as claimed in claim 48 further comprising a resilient spacer [(126)] between the needle and the receptacle.

51. (Currently Amended) A packaged drug as claimed in [any of] claim[s] 48 [to 50] further comprising a resilient means [(114)] associated with the needle such that the needle is automatically withdrawn after use.

52. (Currently Amended) A packaged drug as claimed in ~~any of claims~~ claim 48 [to 51] in which the needle is sharp at both of its ends.

53. (Currently Amended) A packaged drug as claimed in claim 38 comprising a receptacle having a breakable base [(122)] and being sealed by the drive pin [(108)] or other element which drive pin or other element comprises an elongate body [(127)] and a plurality of flexible arms [(128)].

54. (Currently Amended) A packaged drug as claimed in claim 53 in which the arms [(128)] of said element [(108)], in use, ride over one or more ramped surfaces [(130)] provided on the housing such that they are displaced and/or break away from the elongate body [(127)] so the elongate body of the drive pin can travel down the receptacle [(120)], causing the drug [(16)] to be expelled from the base [(122)] of the receptacle which breaks under the pressure exerted thereon.



55. (Currently Amended) A packaged drug as claimed in claim 53 [or 54] further comprising a pioneer projectile ~~[[ (110) ]]~~ below the base of the receptacle.

56. (Currently Amended) A packaged drug as claimed in claim ~~any of claims~~ 38[-55] wherein a placebo is disposed behind the drug ~~[[ (16) ]]~~.

57. (Currently Amended) A method of delivering a drug to a human or animal body through the skin comprising administering a drug using a device as claimed in ~~any of claims~~ claim 1 [to 37] or a packaged drug as claimed in ~~any of claims~~ claim 38 [to 56].